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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,757	08/09/2001	Todd K. Whitehurst	AB-124U1	5963
23845	7590	06/14/2004	EXAMINER	
ADVANCED BIONICS CORPORATION 25129 RYE CANYON ROAD VALENCIA, CA 91355			BOCKELMAN, MARK	
			ART UNIT	PAPER NUMBER
			3762	3

DATE MAILED: 06/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/927,757

Applicant(s)

WHITEHURST ET AL.

Examiner

Mark W Bockelman

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15- 17, 19-24, 31, 33-35 and 37-42 is/are rejected.
- 7) ☒ Claim(s) 14, 18, 25-30, 32, 36 and 43-48 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 recites the limitation "the sensed condition" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 13, 15, 17, 24, 31, 33-35, 39, 42 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Creasy "Electrical Stimulation of Sacral Roots for Micturition after spinal chord Injury".

Creasy teaches the implantation of a Finetech-Brindley stimulation system with positioning of the electrodes intradurally wherein the electrode extends through the dura through a grommet see page 507 column 2 first paragraph. Although not explicitly stated it is apparent that the turning on and off of the device constitutes "at least one pulse" which would inherently travel across the dura through the grommet portion. Penile erection was observed (Page 511). As noted by applicant, the procedure is *usually* accompanied by posterior rhizotomy which suggest that sometimes it is not. Thus the limitations of claim 13 wherein the posterior roots are left in tact are met.

Claims 13, 15-17, 21, 24, 31, 33-35, 39 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tai et al "Penile Erection Produced by Microstimulation of the Sacral Spinal cord of the Cat" in further view of Cameron et al "Micromodular Implants to provide Electrical Stimulation of Paralyzed Muscles and Limbs, or Creasy "Electrical Stimulation of Sacral Roots for Micturition after spinal chord Injury, or Meloy et al USPN 6,169,924. Tai teaches the intradural placement of electrodes into the ventral root of the s1-s3 segments to effect penile erection. No dorsal roots are damaged. The signals are carried across the dura to provide stimulation. Applicant differs in reciting that the stimulator is implanted in the patient. It was well known, as evidenced by Creasy Meloy and Cameron to place the stimulator

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itself within the patients body. To have provided an implanted stimulator in the Tai et al method for long term study and to reduce risks of infection would have been obvious.

Claims 19-20, 22-23, 34-35, 37-38, 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Creasy "Electrical Stimulation of Sacral Roots for Micturition after spinal chord Injury", or alternatively Tai et al "Penile Erection Produced by Microstimulation of the Sacral Spinal cord of the Cat" in further view of Cameron et al "Micromodular Implants to provide Electrical Stimulation of Paralyzed Muscles and Limbs, or Creasy "Electrical Stimulation of Sacral Roots for Micturition after spinal chord Injury, or Meloy et al USPN 6,169,924. as applied above, either in view of Lue et al "Electrostimulation and Penile Erection of Meloy et al US 6,169,924

Applicant differs in reciting various stimulation areas outside the S1-S4 area of the base references and including the T1-L3 segments. Lue et al and Meloy et al both teach such area to be likely segments for success in treating erectile dysfunction and therefore would be obvious alternative stimulation areas to the base references for achieving the desired results.

Claims 1-6, 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Creasy "Electrical Stimulation of Sacral Roots for Micturition after spinal chord Injury" or Tai et al "Penile Erection Produced by Microstimulation of the Sacral Spinal cord of the Cat" either in further view of Cameron et al "Micromodular Implants to provide Electrical Stimulation of Paralyzed Muscles and Limbs. Creasy and Tai each teach the

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implantation of electrodes and generating and delivering pulses to nerves into various spinal segments to effect penile erection. Providing power to the system is inherent. Applicant differs in reciting that the implant is sized so as to be deliverable through a hypodermic tube. Cameron et al teaches a microstimulator that is sized to be inserted through a hypodermic tube which includes all the necessary power and electronics to deliver pulses to nerves. To have made the implanted stimulator of Crease a size that can be delivered through a hypodermic tube or to have used such a device in the Tai et al disclosure would have been obvious in light of the fact that the Cameron device is utilized for treating sacral anterior nerve roots for sexual function, the same results desired by Tai and Creasey. To have provide a sensor for detecting the transmission of data and or power and/or for detecting when a transdermal controller is position thereby would have been obvious

Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Creasy "Electrical Stimulation of Sacral Roots for Micturition after spinal chord Injury" or Tai et al "Penile Erection Produced by Microstimulation of the Sacral Spinal cord of the Cat" either in further view of Cameron et al "Micromodular Implants to provide Electrical Stimulation of Paralyzed Muscles and Limbs as applied to claims 16, 9-11 above, and further in view Meloy et al USPN 6,169,924 or Lue et al "Electrostimulation and Penile Erection". Applicant differs in reciting various spinal segments T10-T-12 and L1-L4 as spinal segments to effect penile erection, such segments being taught by Lue et al rendering the selection of spinal segment obvious.

Allowable Subject Matter

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Claims, 14,18,25-30, 32, 36, 43-48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 12 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W Bockelman whose telephone number is (703)-308-2112. The examiner can normally be reached on Monday - Thursday 10-8:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWB

May 31, 2004


MARK BOCKELMAN
PRIMARY EXAMINER